K022272

Section 2: 510(k) Summary and Certification

JAN 0 8 2003

510(k) Summary

Medtronic

510(k) Summary
[As Required by *21 CFR 807.92*]

Submitter: Roger Brink
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

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Date Summary Prepared: July 11, 2002

Trade Name of Device: Medtronic DLP Malleable Single Stage Venous Cannula

Common Name of Device: Cardiovascular cannula

Classification Name of Device: "Cardiopulmonary bypass vascular cannula," Class II at *21 CFR 870.4210*

Predicate Substantially Equivalent Devices: Medtronic DLP Single Stage Venous Cannulae, Class II at *21 CFR 870.4210,* cleared under 510(k) Number K845045

Description of Device: The Medtronic DLP Malleable Single Stage Venous Cannulae represent modified versions of existing Medtronic Single Stage Venous Cannulae. The proposed change involves the incorporation of a malleable wire/tube assembly embedded within the wall of the cannula. This malleable wire/tube assembly allows the cannula body to be shaped into a surgeon preferred position.

Intended Use of Device: These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery.

Comparison to Existing Predicate Devices K845045 ?

The Medtronic DLP Malleable Single Stage Venous Cannulae are substantially equivalent to existing Medtronic DLP Single Stage Venous Cannulae. The existing

cannulae have been modified to include a malleable wire/tube assembly embedded within the cannula body. The indications for use for both the existing and modified devices are identical, and the addition of wire / tube assembly does not represent a change to the fundamental scientific technology of the devices.

Summary of Non-Clinical Performance Data

Material biocompatibility was conducted in accordance with the ISO 10993-1 standard. Under this standard these cannulae are categorized as externally communicating devices in contact with circulating blood for a limited (<24 hour) contact duration.

Conclusions of Non-Clinical Tests

The results of the non-clinical tests summarized above support an assertion that the Medtronic DLP Malleable Single Stage Venous Cannulae are as safe and effective as the existing Medtronic DLP Single Stage Venous Cannulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2003

Medtronic, Inc.
c/o Mr. Roger W. Brink
Director, QA/RA
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

Re: K022272
Trade Name: Medtronic Malleable Single Stage Venous Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula or Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: October 18, 2002
Received: October 21, 2002

Dear Mr. Brink:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022272

Device Name: Medtronic Malleable Single Stage Venous Cannulae

Indications for Use:

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022272

Prescription Use X OR Ov er-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)